

EXHIBIT 1

CSU: [REDACTED] implants.

Preparation of Photo-fix matrix.

Nucleus tissue was extracted from hog porcine spines. The tissue was extracted under aseptic conditions in the hood and placed in dialysis tubing.

The tissue was treated with HSHS until photo-fixation. Prior to photo-fixation the tissue was removed from HSHS and soaked in MB/PBS for 24 hours.

Photo-oxidation was carried out for 72 hours under halogen lights.

After photo-fixation the tissue was kept in 50%EtOH for 24-48 hours, aliquoted to eppendorf tubes and lyophilized.

After lyophilization the tissue was freezer mill pulverized.

Batches used in the matrix preparation:

HPN980619- 0.455gm

HPN980624- 0.056gm

HPN980710- 0.133gm

HPN980714- 0.173gm

HPN980721- 0.240gm

HPN980803- 0.290gm

Different batches were mixed and weighed. Final weight was 1.22gm.

Sterilization procedure.

[REDACTED]
The tissue was sterilized with 70% isopropanol in a 50ml centrifuge tube.

1st wash: 40ml 70%isopropanol; 1 hr wash on the shaker.

2nd wash: 40ml 70%isopropanol; 1hr wash on the shaker.

All steps including this one are now performed under aseptic conditions (hood).

After each wash the tissue was spun down at 3000rpm for 15min.

The 70% isopropanol was gradually washed out from the tissue with washes in PBS.

Sterile Dulbecco's PBS was added to the pellet; 1hr wash on the shaker.

Followed by o/n wash in DPBS at 4°C (tissue had swollen up).

[REDACTED]
Final wash in DPBS for an hour on the shaker.

The pellet, which had swelled to a final volume of 10 ml, was then resuspended in PBS and the mixture was split to (2) 15 ml centrifuge tubes. Mixture was spun down and PBS decanted.

Volume of pellet in each tube was 3ml. One pellet was frozen down at -80°C for later use.

The second pellet was resuspended in 3ml of sterile sheep serum and washed for an hour at 4°C. The mixture was spun down and the supernate was decanted.

Matrix/BP/Serum: 12.5ul of 20mg/ml BP was dissolved in 3ml of unsterile serum (serum was'nt heat denatured). This BP/serum mixture was sterile filtered onto the pellet and the pellet was evenly distributed into the BP/serum mixture. The final volume of the mixture was 5ml, which contained BP at a concentration of 50ug/ml.

This mixture was then aliquoted to 4 cryovials and frozen down at -80°C. 3 vials will be used for the implants while the fourth vial will be used for lab studies to test the sterility and effect of BP. The tissue was shipped out on [REDACTED].

Lots

MPBP970115

DPBS 1013685 (Life Tech)

Isopropanol (99.9%) B0070276 (ACROS)

Sheep serum from Turner [REDACTED]

Implants

Matrix used for animal implants at CSU on [REDACTED]

[REDACTED] sheep were implanted with tissue. Per animal there was around 200 ul of tissue.

Stab, normal, stab+tissue.

From the four vials sent three came back. They were frozen down.